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K021593

Attachment - 4

510(k) Summary of Safety and Effectiveness

General Provisions	Trade Names: Vista Brite Tip® and Envoy® Guiding Catheters Common/Classification Name: Percutaneous Catheter
Name of Predicate Devices	• Vista Brite Tip® and Envoy® Guiding Catheters
Classification	Class II
Performance Standards	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Percutaneous Catheters.
Intended Use and Device Description	Vista Brite Tip - The guiding catheter is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems. Envoy – The Envoy guiding catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional / diagnostic devices. Device Description: • 6 French (ID 0.070"); • Single lumen catheter with a reinforced body (tightly wound stainless steel braid wire); • Catheter body transitions provide a gradual decrease in material stiffness (varying durometers) from the body to the tip; and, • Polycarbonate hub.
Biocompatibility	All materials used in the these devices are biocompatible.

Continued on next page

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Attachment - 4 – 510(k) Summary of Safety and Effectiveness, continued

Summary of Substantial Equivalence	The Cordis Vista Brite Tip® and Envoy® Guiding Catheters are substantially equivalent to the previously cleared Cordis Vista Brite Tip® and Envoy® Guiding Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2002

Cordis Corporation
Stephen M. Enos, RN
Manager, Regulatory Affairs
14201 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K021593
6F (0.070") Vista Brite Tip® and Envoy® Guiding Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: 74 DQY
Dated: May 14, 2002
Received: May 15, 2002

Dear Mr. Enos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 021593

Attachment - 2

Indications for Use Statement

510(k) Number (if known)	The 510(k) number has not yet been assigned.
Device Name	6F (0.070") Vista Brite Tip® and Envoy® Guiding Catheters
Indications for Use	Vista Brite Tip - The guiding catheter is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems. Envoy – The Envoy guiding catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional / diagnostic devices.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021593

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)